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| 10/592,953 | 03/01/2007 | Eiji Nogami | 24-038-TN | 8665 |
| 23400 7590 04/20/2009 POSZ LAW GROUP, PLC 12040 SOUTH LAKES DRIVE SUITE 101 RESTON, VA 20191 | | | EXAMINER LEA, CHRISTOPHER RAYMOND | |
| | | | ART UNIT 1619 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/592,953

Applicant(s)

NOGAMI, EIJI

Examiner

Christopher R. Lea

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 11/12/2008 & 4/7/2009
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This application is a 371 (national stage application) of PCT/JP05/04567.

Receipt of Amendments/Remarks filed on January 12, 2009, is acknowledged. In response to Non-final office action dated September 12, 2008, applicant amended claim 1 and added new claims 5-8. Claims 1-8 are pending. Claims 1-8 are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. All new rejections applied have been necessitated by applicant's amendment to the claims. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on November 12, 2008, and April 7, 2009, were filed after the mailing date of the first Office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to add the word "layer" in line 10 and also in lines 14 & 15. These additions render the claim indefinite and confusing. It appears to the examiner that applicant has confused the first and second intermediates with the optional intermediate layers which are part of the first and second intermediates. This confusion arises from the use of "intermediate" as both a noun and adjective in the claim. As the examiner understands the claim, when intermediate follows the words "first" or "second" it is a noun meaning a product of one of a series of steps. When intermediate is used to describe a layer as in "via an intermediate layer" it is an adjective meaning existing between. The examiner believes the amendment muddies this distinction, and is in fact inappropriate. The examiner believes it would be remedial to delete the word "layer" from line 10 and delete the second instance of the word "layer" from lines 14 & 15 of the claim. The examiner will interpret the claim in this manner, i.e., ignoring the words "layer" that were added in the latest amendment. Since claims 2-8 ultimately depend from claim 1, they have been rejected under 35 U.S.C. 112 second paragraph as well.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nogami (EP 1391212, which is available under 102(b) either itself or as translation WO document 02/087622, and is equivalent to US PreGrant Publication 2004/0137040 and its correction 2008/0254102, all references below refer to the EP document).

Applicant claims

Applicant claims a method for producing a multi-layered pharmaceutical composition which comprises joining two drug-containing intermediates via heat fusion. Applicant further claims specific properties for the layers of the composition.

Determination of the scope and content of the prior art (MPEP 2141.01)

Nogami teaches, as a whole, a method for producing a multi-layered pharmaceutical composition by joining two drug containing intermediates via heat fusion.

Claim 1-4: Nogami teaches as method wherein a water-swellaible gel-forming layer (functional layer) is formed onto a plastic film, mount or other support, and a drug-containing layer is then formed onto the water-swellaible gel-forming layer. Next, an adhesive layer applied onto the drug-containing layer. An intermediate is thus produced comprising a water-swellaible gel-forming layer, a drug-containing layer and an adhesive layer layered in that order on a support. The above step is repeated to form another intermediate and the adhesive layers of two intermediates are then heat-fused to one another (all in paragraph 81). Nogami further teaches polyvinylpyrrolidone (a thermoplastic edible polymer) as a possible base for the drug-containing layer; however, Nogami places not particular limitations on the base of the drug-containing layer (paragraph 28-9). Further, Nogami suggests a form where two drug layers are in proximal contact (paragraph 59).

Claim 5: Nogami teaches making the drug-containing layer film-shaped (paragraph 32) and using an edible polymer as a base (paragraph 31). Nogami teaches that film-forming agents (including polyvinyl acetate) improve the film-forming properties of a layer (paragraphs 42 & 43). Nogami teaches polyvinyl acetate and vinylpyrrolidone-vinyl acetate copolymer as possible bases for adhesive layers (paragraph 62). By applicant's admission, polyvinyl acetate is thermoplastic and edible. Since Nogami teaches polyvinyl acetate's suitability to be included in the oral agent and its ability to improve a desired property of the drug-containing layer, the inclusion of polyvinyl acetate in the drug-containing layer would have been prima facie obvious, especially in the absence of evidence to the contrary.

Claims 6-8: Nogami teaches thermally-fusing two intermediates together (paragraph 81); therefore, it would be within the purview of the skilled artisan to discover the workable ranges for this process through routine experimentation, especially in the absence of a showing of the criticality of the claimed ranges.

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the instant application and Nogami is that Nogami does not expressly teach heat-fusing the two drug-containing layers directly.

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to heat-fuse the drug-containing layers directly, without the aid of adhesive layers, and produce the instant invention. The skilled artisan would have been motivated to do this because the amount of labor used to produce a layered composition is necessarily tied to the number of layers in the composition. Therefore market forces would pressure the skilled artisan to eliminate the adhesive layers while still maintaining the ability to heat-fuse the two intermediates. Selecting a drug-containing layer base that is thermoplastic and heat-fusible is certainly within the purview of the skilled artisan, therefore, the omission of the adhesive layers would be *prima facie* obvious to the skilled artisan, absent evidence to the contrary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in combining the functions of the drug-containing layer with the function of the adhesive layer into one layer and producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Response to Arguments

7. Applicant's arguments filed January 12, 2009, have been fully considered but they are not persuasive. Applicant argues that the present invention overcomes a shortcoming of the Nogami prior art. Applicant argues that the time required for drying the individual layers results in increased instability of the active agent. However, applicant provides no evidence that this problem exists or that the instant invention solves it. "[T]he arguments of counsel cannot take the place of factually supported evidence" (See MPEP § 2145). "Applicants who allege they discovered the source of a problem must provide evidence substantiating the allegation, either by way of affidavits or declarations, or by way of a clear and persuasive assertion in the specification" (See MPEP § 2141.02 IV). In the instant case, applicant asserts an increase in drug destabilization; however, there are no examples of this problem cited, nor are any active

agents disclosed to suffer from this problem. It seems unlikely that all the active agents disclosed in either the Nogami prior art or the instant specification suffer from this instability while drying. In the absence of this evidence, the examiner is not persuaded that the claimed invention is unobvious in view of the Nogami prior art, and for this reason the rejection under 35 U.S.C. 103(a) is maintained.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-21 of copending Application No. 10/690,811. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '811 application are

drawn to orally administered agent which is produced via a method similar to the instant claims. The difference between the claims is that the claims of the '811 application involve the heat fusion of intermediate layers between the drug-containing layers and the instant claims heat fuse drug-containing layers. It would have been prima facie obvious to combine the function of intermediate (adhesive) layer and the drug-containing layers of the '811 application in order to produce the instant claims where the drug-containing layers are heat fused, in order to save time and labor cost.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-8 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

***/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616***